PATENT APPLICATION

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8/21/98
Date

Phillip B.C. Jones

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : James W. Baumgartner *et al.*
Serial No. : 08/815,773
Filed : March 12, 1997
For : Testis-Specific Receptor

Examiner : E. Lazar-Wesley, Ph.D.
Art Unit : 1646
Docket No. : 95-33

Assistant Commissioner for Patents
Washington, D.C. 20231

Declaration Under 37 CFR §1.131

Sir:

We, James W. Baumgartner, Theresa M. Farrah, Donald C. Foster, Frank J. Grant, and Patrick J. O'Hara, do hereby declare as follows:

1. We are the named inventors of the above-identified patent application.

2. All of the work described herein and illustrated by the attached exhibits was performed in the United States of America under our direction.

3. Exhibit 1 comprises copies of slides prepared by one of us (Donald C. Foster) for an in-house seminar on the WSXWS Receptor Project, which was presented before March 1, 1996. The slide entitled "The WSXWS Receptor Project Seeks to Identify Novel Therapeutics Which Play Important Roles in Tissue

Regeneration" shows that an objective of the project was to use novel receptors to find novel cytokine ligands. The slide entitled "Three Novel Receptors in the WSXWS Family Offer Potential for Three Novel Cytokine Therapeutics" shows that Zcytor2 was part of the WSXWS Receptor Project. Exhibit 2 is a copy of a portion of a memo written by one of us (Frank J. Grant) before March 1, 1996, regarding particular goals for the WSXWS project. According to the memo, soluble forms of a receptor can be labeled and used as a probe to detect the cognate ligand (see Exhibit 2, fourth paragraph). Finally, Exhibit 3 is a copy of a printout of the nucleotide sequence of a Zcytor2 clone corresponding to SEQ ID NO:1, which encodes the amino acid sequence of SEQ ID NO:2. This nucleotide sequence was printed before March 1, 1996. Taken together, these exhibits evidence conception of a method to detect a ligand by contacting a test sample with a polypeptide comprising the extracellular ligand binding domain (*i.e.*, soluble receptor) of Zcytor2 (claims 33 and 34).

4. In Exhibit 1, the WSXWS Receptor Project slide entitled "Expression Cloning Assay for Orphan Receptor Ligands" shows a "new receptor" with extracellular, transmembrane, and cytoplasmic domains expressed in a cell prepared for a ligand assay. Accordingly, the slide shows a ligand detection method using a receptor comprising extracellular, transmembrane, and cytoplasmic domains (claim 35). Moreover, the slide shows that the expression assay measures a biological response to ligand treatment (claim 36). Since the exemplary biological response is cell growth, the slide also describes the subject matter of claim 37.

5. Exhibit 2 (fourth paragraph) states that a WSXWS receptor can be attached to a solid support in order to purify the cognate ligand. Exhibit 4 is a copy of a page from the notebook of Cameron Brandt, a research associate who produced the Zcytor2 receptor/Ig heavy chain fusion protein described in the above-captioned application. Cameron Brandt provided the fusion protein as part of the WSXWS Receptor Project effort under our supervision. The first paragraph of Exhibit 4, written before March 1, 1996, states that:

> Will build a vector for expression of soluble receptors fused to IgG gamma 1 heavy chain. This expression system allows an easy way to purify soluble receptors over a protein A column and then provides a handle for using in going after ligand.

Accordingly, Exhibits 2 and 4 evidence the conception of a method for using an immobilized receptor to bind ligand from a test sample. While the focus of the submitted statements is on ligand purification, it is clear that bound ligand must be detected as part of the purification process.

6. On the basis of these exhibits which document activities within the United States of America, we conclude that the invention described in claims 33-38 of the above-captioned application was at least conceived before March 1, 1996.

7. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that the making of willfully false statements and the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and may jeopardize the validity of any patent issuing from this patent application.

James W. Baumgartner	Date
Theresa M. Farrah	Date
Donald C. Foster	8/20/98 Date
Frank J. Grant	Date
Patrick O'Hara	Date